

DATA EVALUATION RECORD

STUDY 11

CHEM 112600 Prohexadione calcium
CAS No. 127277-53-6
FORMULATION-00-ACTIVE INGREDIENT

STUDY MRID 44725215

Perez, R. and J. Patel. September, 1998. Storage stability study of Prohexadione Calcium (BAS 125 W) in soil in support of field soil dissipation studies. Performed by ADPEN Laboratories, Inc., Jacksonville, FL. Submitted by BASF Corporation. RTP, NC. BASF Reg. No. 97/5309 and Report No. 96056. 52 pp.

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GENERAL:

Freezer storage stability studies are needed to support Subdivision N guideline studies.

CONCLUSIONS:

Ancillary Study - Freezer Storage Stability

1. EFED concludes that this supplemental study (Subdivision N, 164-1) is acceptable.
2. BAS 125 W is stable in soil for 12 months and fairly stable for 17 months when stored frozen at -23 to 0 °C. The total average corrected recoveries of BAS 125 W in soil were

95%, 89%, and 84.9% at 3, 12, and 17 months, respectively.

3. No additional information on the freezer storage stability of BAS 125 W in soil is required at this time.

METHODOLOGY:

California (a San Joaquin soil from Tulare County several miles south from Porterville; RCN 96044, MRID 44725213) control soil core samples from field trials were used in this study. Control soil samples were divided into seventy 20 g samples, fortified with 1.00 ppm BAS 125 W, and together with unfortified control samples stored frozen at -23 to 0 °C. The storage temperature on two occasions was higher than 0 °C (0 - 8 °C and 0 - 1 °C for 2 hours on 12/12/97 and 1 hour on 1/5/98, respectively) due to a freezer repair. Stored samples were analyzed for BAS 125 W at 0, 7, 13 days; 1, 3, 6, 11, 12 and 17 months. BASF's analytical method D9067 was used for the analysis.

Thawed samples were extracted twice with 50 ml of 0.1 N ammonium bicarbonate, centrifuged, and decanted supernatants were combined. Acidified supernatants to pH 2 were fractionated using a SAX SPE column that was conditioned with methanol and water at pH 2. Samples were eluted with pH 2 water, the eluates were divided onto two aliquots from which one was refrigerated. The second aliquot was extracted three times with ethyl acetate. Prior to the extraction 4 ml of concentrated sulfuric acid and 20 g of sodium chloride was added to the aliquot. The combined ethyl acetate extracts were filtered through a PS-1 filter with sodium sulfate. The filtrate was concentrated to dryness and the residue was dissolved in 1% acetic acid in HPLC grade water. An aliquot was analyzed for BAS 125 W via HPLC with column switching (100 mm Hypersil ODS C18 column as a precolumn, 250 mm Kromasil C18 column as an analytical column) and UV detection on HP 1050 and 1100 series liquid chromatographs (acetonitrile:1%acetic acid, 30:70, as a mobile phase). For integration and calibration of peaks an HP Multi Instrument ChemStation Data System was used.

Procedural recoveries for this analytical method averaged $83.3 \pm 5.6\%$ (n=18) of BAS 125 W. The limits of quantitation were 0.01 ppm of BAS 125 W.

DATA SUMMARY:

The average corrected recoveries (average corrected recovery = (average stored recovery/average procedural recovery) x 100) of BAS 125 W in soil were as follows: time 0: 106.1%, 7days: 97.4%, 13 days: 98%, 1 month: 89.2%, 3 months: 95%, 6 months: 94.8%, 11 months 89.7%, 12 months: 89%, and 17 months: 84.9% (see attached Table 1). Procedural recoveries were corrected for the control sample residues.

REVIEWER'S COMMENTS:

1. BAS 125 W is stable in soil for 12 months and fairly stable for 17 months when stored frozen at below -5°C . The total average corrected recoveries of BAS 125 W in soil were 95.0%, 89.0%, and 84.9% at 3, 12, and 17 months, respectively.

Prohexadione Calcium

DER MRID 44725215

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